AUG 2 5 2000

510(K) SUMMARY

WizAir™ Ambulant Pneumatic Compression System

510(k) Number K002287

Applicant's Name:

Medical Compression Systems (DBN) Ltd.
9 Harugei Malhut st.
Tel-Aviv 69714, Israel
Tel.: 972-3-647-1615
Fax: 972-3-647-0293

Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131

Date Prepared:

July, 2000

Trade Name:

WizAir™ Ambulant Pneumatic Compression System

Classification Name:

Compressible Limb Sleeve

Classification:

Class II; Product Code JOW; Regulation No. 870.5800.

Statement of Substantial Equivalence:

The ***WizAir***™ Ambulant Pneumatic Compression System is substantially equivalent in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc., to the commercially available ***ProAir 3000*** Compression System. The changes between the two systems include reduction of the compression time, inclusion of a pneumatic connector, and change in pump and sensors.

Device Description:

The ***WizAir***™ is a prescriptive, pneumatic compression device designed to apply sequential compression to the lower limb. The control unit of the ***WizAir***™ is light and compact, thus making it a portable ambulant system. The ***WizAir***™ provides the user with an option of battery operation in addition to the operation from the mains option. The ***WizAir***™ is easy to use and provides the user with three treatment options: compression of the foot, compression of the calf, or combined compression of both (one foot and one calf).

The foot compression program is sequential intermittent pressure pulse application to a single celled foot cuff. The calf compression program is a sequential intermittent gradient application of a pressure to a three celled calf cuff.

The device is composed of four main sub-systems:

1) A portable pneumatic control unit,
2) A pair of cuffs (calf and/or foot-ware),
3) Pneumatic connecting tubes and
4) An electrical DC transformer.

Inflation and deflation of the cuff's cells are controlled by the control system. The inflation and deflation sequence produces a massage on the patient limb in order to stimulate the natural flow of the body fluids.

Indications:

The ***WizAir***™ is a prescriptive device that induces controlled compression of the calf, the foot or combined compression of both.

The ***WizAir***™ is intended for use by patients and medical professionals in treating many conditions, such as:

- prevention of deep vein thrombosis (DVT)
- enhancement of blood circulation
- reduction of post-operative pain and swelling
- reduction of wound-healing time
- stasis dermatitis
- treatment and assist healing of cutaneous ulceration
- venous stasis ulcers
- leg ulcers

- chronic venous insufficiencies
- reduction of edema

Contraindications:

The ***WizAir™*** system should not be used in the following cases:
Gangrene, recent skin graft, severe arteriosclerosis or other ischemic vascular disease, congestive cardiac failure, massive edema, pulmonary edema, existing DVT, acute thrombophlebitis, acute infections, and during episodes of pulmonary embolism.

Performance Data:

A series of safety and performance testing including comparative analysis between the ***WizAir™*** and the ***ProAir 3000*** demonstrated that the ***WizAir™*** is substantially equivalent to the ***ProAir 3000*** without raising new safety and/or effectiveness issues

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2000

Medical Compression Systems (D.B.N) Ltd.
c/o Ms. Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah Street
Ra'anana 43373, Israel

Re: K002287
WizAir™ Ambulant Pneumatic Compression System
Regulatory Class: II (two)
Product Code: JOW
Dated: July 27, 2000
Received: July 27, 2000

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K002287

Device Name: *WizAir*™ Ambulant Pneumatic Compression System

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- venous stasis ulcers
- leg ulcers
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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002287

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Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)